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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/671,913

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EXAMINER

TYSON, MELANIE RUANO

ART UNIT

PAPER NUMBER

3773

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/671,913	<b>Applicant(s)</b> SOLAR ET AL.	
	<b>Examiner</b> Melanie Tyson	<b>Art Unit</b> 3773	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5,6,8-12,14-17,19,20,22,23,25 and 35-59 is/are pending in the application.
- 4a) Of the above claim(s) 8,10,20,22,23,25,35,42,47-52 and 55-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,9,11,12,14-17,19,36-41,43-46,53,54,58 and 59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 January 2007 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

This action is in response to the applicant's amendment received on 31 October 2008 and election received 02 March 2009. Claims 4, 7, 13, 18, 21, 24, and 26-34 remain canceled. Claims 8 and 10 remain withdrawn from consideration. New claims 58 and 59 have been added. The amendments made to the claims do not place the application in condition for allowance for the reasons set forth below.

### ***Election/Restrictions***

Claims 22, 23, 25, 35, 42, and 47-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02 March 2009. In contrast to the applicant's remarks, claim 20 reads on non-elected species 3 and claim 57 reads on non-elected species 2, thus are also withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species. Claims 55 and 56 combine species 1 and 3, thus are also withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species. For continuation purposes, let it be noted that species 1 and 3 were not disclosed as being combinable at the time the application was filed.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the one or two standoff

features, one or two relief openings, and two members must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The groove defined in an external perimeter of the base unit, wherein the elastomer band is positioned within the groove and extends across the

passage to engage the attaching device (see claims 41 and 46) as shown in Figure 3A is not appropriately described in the specification.

### ***Claim Objections***

Claims 1 and 36 are objected to because of the following informalities:  
typographical errors due to amendments made. In claim 1, remove the term "with" from amended portion "a deformable substantially spherical socket for engaging [with] the spherical portion." In claim 36, insert the term --substantially-- before the term "spherical." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 6, 11, 12, 14-16, 17, 19, 20, 38-41, 43-47, 53, 54, 55, 56, 58, and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Claims 2, 6, 11, 12, 14-16, 17, 19, 20, 38-41, 43-47, 53, 54, 55, 56, and 59 contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims contain subject matter of "at least one relief opening," "at least two standoff features," and "a standoff feature." The specification does not enable for "one or two relief openings" and "one or two standoff features" in such a way as to enable one skilled in the art to which it

pertains of how the invention is made or used with one relief opening, two relief openings, one standoff feature, and two standoff features.

Claim 58 is also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. At the time the application was filed, the applicant failed to disclose the deformable socket is operable to allow the guide axis to be positioned in at least two angles relative to the base unit. Therefore, this limitation is considered new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 40 recites the limitation "the relief opening" and claim 41 recites the limitation "the elastomer band." There is insufficient antecedent basis for these limitations in the claims. With further respect to claim 40, it is unclear as to how the spherical socket includes at least two members if there is only one relief opening that completely dissociates the members.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-3, 5, 6, 9, 11, 15, 16, 36, 38-40, and 58** are rejected under 35

U.S.C. 102(b) as being anticipated by **Mowlai-Ashtiani (U.S. Patent No. 6,110,182)**.

Mowlai-Ashtiani discloses an alignment device (see entire document) comprising a longitudinal guide portion (72), a spherical portion (32), a base unit including a deformable substantially spherical socket for engaging the spherical portion (for example, Figure 1) and connected to (via 78) and extending from a first side of a substantially planar portion (ring 80) operable to allow the guide axis to be position in different angles relative to the base unit, and an actuating device (threaded locking ring 52 + washer 60) surrounding and engaging an outer perimeter of the socket (for example, see Figure 2; washer surrounds and engages a portion of the perimeter thus satisfies the recited limitation), wherein the actuating device has the ability to cause substantially symmetric tightening of the spherical socket, and a number of standoff features attached to the base unit (for example, see Figure 1; portions on either side of head, wherein the circular portion with screw securing devices disposed in a passage may contact the work surface along a circle) extending from a second side of the planar portion (80) to position the planar portion a distance away from the skull, and at least one relief opening (20, 22, 24 substantially equally spaced, wherein 20 defines a complete passage between at least two members).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1, 3, 5, 9, 37, and 58** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Henderson et al. (U.S. Publication No. 2003/0114752 A1)** and **Ghajar et al. (U.S. Patent No. 4,998,938)**.

Henderson discloses an alignment device (see entire document) comprising a longitudinal guide portion (424), a spherical portion (528), and a base unit including a deformable substantially spherical socket portion (the combination of 1040 and 1050 form the socket for the spherical portion wherein portion 1050 engages the spherical portion) in that it compresses when a threaded actuating device (locking ring 432) having engaging threads is screwed over it (over portion 1040) to engage threads disposed on an outer perimeter of the spherical socket (thus is not in direct contact with



the socket), wherein the actuating device has the ability to cause substantially symmetric tightening of the spherical socket, and a substantially planar portion (140) in which the deformable spherical socket extends from a first side (the top side).

Henderson fails to disclose a number of standoff features attached to the base unit extending from a second side (the bottom side) of the substantially planar portion to position the substantially planar portion a distance away from the skull.

Ghajar discloses an alignment device (see entire document) comprising a longitudinal guide portion (12) and a base unit having a substantially planar portion (22). Ghajar teaches a number of standoff features (20) adapted to contact the work surface along a circle extending from a second side (the bottom side) of the substantially planar portion to position the substantially planar portion a distance away from the skull (for example, see Figure 5). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Henderson's device with a number of standoff features as taught by Ghajar. Doing so would minimize contact between the device and the patient's skull, thus reducing the risk of infection (for example, see column 2, lines 44-48).

**Claims 2, 6, 36, and 38** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Henderson et al.** and **Ghajar et al.** as applied to claim 1 above, and further in view of **Mowlai-Ashtiani**.

Henderson in view of Ghajar discloses the claimed invention except for relief openings in the spherical socket. Mowlai-Ashtiani discloses an alignment device (see entire document) comprising a guide portion (72), a spherical portion (32), and a deformable socket (10). Mowlai-Ashtiani teaches three relief openings in the spherical socket, one of which forms a complete passage between two sides of the socket, thus forming a discontinuity in the sphere (for example, see Figure 3). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the spherical socket of Henderson in view of Ghajar having relief openings as taught by Mowlai-Ashtiani. Doing so would help to maintain the structural integrity of the spherical socket after repeated use (for example, see column 3, lines 40-44).

**Claims 12, 14, and 54** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mowlai-Ashtiani** in view of **Ghajar et al.**

Mowlai-Ashtiani discloses the claimed invention except for three truncated cone shaped standoff features. Ghajar discloses an alignment device (see entire document) comprising a longitudinal guide portion (12) and a base unit having a substantially planar portion (22). Ghajar teaches three truncated cone shaped (wider on top and narrower towards the bottom) standoff members (20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Mowlai-Ashtiani's device with three standoff features, since it has been held that mere

duplication of the essential working parts of a device involves only routine skill in the art. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form Mowlai-Ashtiani's standoff features in a truncated cone shape as taught by Ghajar. Doing so would reduce the contact surface area of the standoff feature, thus minimizing contact between the device and the patient's skull which reduces the risk of infection (for example, see column 2, lines 44-48).

**Claims 17 and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mowlai-Ashtiani** and **Magee et al. (U.S. Patent No. 5,957,927)**.

Mowlai-Ashtiani discloses the claimed invention (see above for similar limitations), wherein the guide axis extends through the center of the base unit between the two standoff features, except for a retention force providing member to retain the attaching device near the passage.

Magee discloses a bone fixation device holder (see entire document). Magee teaches a retaining force applying member for a bone screw (62 and sloped surface protruding into passage 34; for example, see Figure 10) in order to hold the screw while it is initially being driven into bone (for example, see column 5, lines 31-40). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the standoff features of Mowlai-Ashtiani with retention members as taught by Magee. Doing so would assist in proper placement of the retention members prior to being driven into the skull.

**Claims 43-45, 53, and 59** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Henderson et al., Mowlai-Ashtiani, and Magee**.

Henderson discloses an alignment device (see entire document) comprising a longitudinal guide portion (424), a spherical portion (528), a base unit (the combination of all 3 base members having opening 1034) including a substantially planar portion (414), wherein a single deformable spherical socket portion (the combination of 1040 and 1050 form a single deformable socket for the spherical portion) extends from a first portion (top side), a number of securing devices (screws in mounting holes 416), an actuating device including a threaded locking ring (432) surrounding and engaging threads disposed on an outer perimeter of the spherical socket, and a standoff feature (140) extending from a second side (bottom side) of the substantially planar portion adapted to mount directly to a skull of a subject. Regarding claim 53, the standoff feature extends from the base unit a distance, therefore, a portion of the base unit is a distance away from the work surface. Henderson fails to disclose at least one relief opening in a portion of the spherical socket and a retaining force applying member.

Mowlai-Ashtiani discloses an alignment device (see entire document) comprising a guide portion (72), a spherical portion (32), and a deformable socket (10). Mowlai-Ashtiani teaches three substantially equally spaced relief openings in the spherical socket, one of which defines a complete disassociation between two sides of the spherical socket (for example, see Figure 3). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to

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one having ordinary skill in the art at the time the invention was made to construct the spherical socket of Henderson having relief openings as taught by Mowlai-Ashtiani. Doing so would help to maintain the structural integrity of the spherical socket after repeated use (for example, see column 3, lines 40-44).

Magee discloses a bone fixation device holder (see entire document). Magee teaches a retaining force applying member for a bone screw (retaining element 62 and sloped surface of 34; for example, see Figure 10) in order to hold the screw while it is initially being driven into bone (for example, see column 5, lines 31-40). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the standoff features of Henderson with retention members protruding into and extending external to the passage as taught by Magee. Doing so would assist in proper placement of the retention members prior to being driven into the skull.

***Allowable Subject Matter***

Claim 41 would be allowable if the base claim is rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraph, set forth in this Office action, and if claim 41 is rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Claim 46 would be allowable if the base claim is rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraph, set forth in this Office

action, and if claim 46 is rewritten to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose, in combination with the other limitations in the claims, a groove defined in an external perimeter of the base unit, wherein the retaining force applying member includes an elastomer band and the elastomer band is positioned within the groove and extends across the passage to engage the attaching device.

### ***Response to Arguments***

Applicant's arguments with respect to claims 17 and 19 have been considered but are moot in view of the new ground(s) of rejection.

The applicant's arguments regarding claims 1 and 11 are moot in view of a new interpretation of the Henderson reference. Both portions 1040 and 1050 are considered to form a spherical socket in which portion 1050 is capable of engaging the spherical portion as claimed.

Regarding claims 43 and 59, the applicant argues that the combination of Magee with Henderson and Mowlai-Ashtiani is improper, since Henderson and Mowlai-Ashtiani are not related to a bone fixation device introducer. However, it is the examiner's position that Magee teaches retaining force applying members are well known and to apply a known technique to a known device requires merely ordinary skill in the art. Doing so would provide the advantages described above (see rejection above).

The applicant's arguments with respect to claims 22 and 55 are moot, since the claims have been withdrawn from consideration.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Friday 7-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./  
Examiner, Art Unit 3773  
May 18, 2009

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773